DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/1/2010 has been entered.

Status of the Claims

2. The amendments filed 2/18/2010 were entered.

Response to Arguments

3. Applicant's arguments, filed 2/18/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. In particular, the rejection of claims under 35 U.S.C. 103(a) as being unpatentable over *Scivoletto* and *Jacobson et al* is withdrawn and the double patenting rejection of claims has been withdrawn. Applicant's arguments directed to a withdrawn rejection are thereby rendered moot. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 13 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by *Jacobson et al* (cited in a previous Action) as evidenced by *Jacobson et al* (in Fundamentals of Cancer Prevention, 2nd Edition, Pages 215-237, 2008)**.

6. As amended, instant claim 13 is drawn to a method for increasing leptin levels in a human subject in need of (A) improved skin epitheliation and (B) increased leptin levels, said method comprising administering (orally or topically) to said subject an amount of nicotinic alkyl ester sufficient to increase leptin levels in said patient and improve skin epitheliation, wherein the alkyl chain of said nicotinic acid alkyl ester contains from 12 to 22 carbon atoms (more specifically, 12 or 14 carbon atoms). As summarized, the invention reads on claims 12 and 18-20.

7. *Jacobson et al* teach pro-NAD pharmaceutical compositions and methods of using said compositions to enhance “dermal and epidermal skin cell NAD content" and “to treat disorders such as sunburn and other skin deterioration” (Abstract) (more specifically “skin deterioration that results from DNA damage to cells of the skin" (Column 1, Lines 27-28)) said method comprising "topically” or “orally” (Abstract) administering a pro-NAD composition to a “human” (Column 6, Line 10). More specifically, *Jacobson et al* disclose a pro-NAD composition comprising **tetradecylnicotinate** (Column 22, Line 50) which enhances skin cell NAD content in a hairless mouse model. Considering that *Jacobson et al* state that "[i]ncreased NAD content of skin correlates with less severe skin deterioration" (Column 18, Lines 36-37), one of ordinary skill in the art would have immediately envisaged practicing the method disclosed by *Jacobson et al* (i.e., treating disorders such as sunburn and other skin deterioration) by administering **tetradecylnicotinate**.

8. Accordingly, *Jacobson et al* teach a method "to treat disorders such as sunburn and other skin deterioration" comprising administering (orally or topically) a nicotinic acid alkyl ester containing 14 carbon atoms to a human subject in need thereof. Notably, Applicant has not defined what is meant by a person in need of improved **skin epitheliation** (which is understood to mean **skin regeneration**). As such, a human subject in need of treatment for sunburn and other skin deterioration is asserted to encompass a human subject in need of improved skin epitheliation. It is also asserted that a human subject in need of treatment for sunburn and other skin deterioration (more specifically "skin deterioration that results from DNA damage to cells of the skin" (Column 1, Lines 27-28)) encompasses a human subject in need of increased leptin levels. As evidenced by *Jacobson et al* (in Fundamentals of Cancer Prevention, 2nd Edition, Pages 215-237, 2008), DNA damage to cells of the skin promotes disruption of epidermal barrier and skin cancers (Page 216, Figure 1). And, as acknowledged by the instant Specification, a person in need of increased leptin includes persons in need of epidermal barrier development and inhibition of skin tumor formation (Page 7, Lines 15-19; see also Figure 1).

9. As such, the **patient population** (i.e., a human subject in need of (A) improved skin epitheliation and (B) increased leptin levels) and **the active step** (i.e., administering (orally or topically) a nicotinic acid alkyl ester having 12 carbon atoms) taught by the prior art are identical to those recited by instant claims 13 and 18-20. As such, the preamble of instant claim 13 is not afforded patentable weight. As noted by the court in *Hoffer v. Microsoft Corp.*, 405 F.3d 1326 (Fed. Cir. 2005), a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited" (quoting *Minton v. Nat 'l Ass 'n of Securities Dealers, Inc.*, 336 F.3d 1373 (Fed. Cir. 2003)). Although the *Hoffer* court was

discussing the weight of a whereby clause, the reasoning applies equally to the weight of a preamble. In the instant case, as discussed above, the preamble (i.e., increasing leptin levels) simply expresses the intended result of a process step positively recited (i.e., administering (orally or topically) a nicotinic acid alkyl ester having 12 carbon atoms to a human subject in need of (A) improved skin epitheliation and (B) increased leptin levels). As noted by the court in *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.,* 814 F.2d 628 (Fed. Cir.), cert. Denied, 484 U.S. 827 (1987), merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. As in *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.,* the burden of proof is limited to establishing that prior art discloses the same process. There is no additional burden of proving that the prior art recognized the administration of the agents of said process functioned in elevating leptin levels, that outcome was inherently achieved by administration of a nicotinic acid alkyl ester having 12 carbon atoms according to the disclosed process, and, thus the prior art process teaches the claimed invention. See also, *In re Woodruff*, 16 USPQ2d 1934 (Fed. Cir. 1990), which states "a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."

10. Accordingly, for all the foregoing reasons, instant claims 13 and 18-19 are anticipated.

11. Instant claim 21 is drawn to the method of claim 13 comprising administering more than one nicotinic acid alkyl ester. As stated in the previous Action mailed on 9/30/2009, *Jacobson et al* specifically teach the administration of a ***combination*** of nicotinic alkyl esters (Column 5, Line 28). Accordingly, instant claim 21 is also anticipated.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. **Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Jacobson et al* (cited in a previous Action) as evidenced by *Jacobson et al* (in Fundamentals of Cancer Prevention, 2nd Edition, Pages 215-237, 2008)**.

15. As discussed above, the method of claim 13 is taught by the prior art. Instant claims 22-24 are drawn to the method of claim 13 wherein the nicotinic alkyl ester is administered in an amount ranging, most specifically, from about 0.4 g to about 5 g/day/70 kg of body weight. Although *Jacobson et al* do not specifically disclose the recited dosage range, determining the optimal dosage range would have been obvious to a person of ordinary skill in the art at the time the invention was made. Indeed, as acknowledged by Applicant in the instant Specification, "[t]he dose can and will vary" (Page 7, Line 25) and, as disclosed by *Jacobson et al*,

"[d]etermination of the effective amounts is well within the capability of those skilled in the art" (Column 13, Lines 1-3). Accordingly, since it would have been *prima facie* obvious to determine the optimal dosage range via routine experimentation, and since there is no assertion that the recited ranges are critical or provide unexpected results, instant claims 22-24 are rejected. See *In re Aller*, 220 F.2d (CCPA 1955) which notes that "is it not inventive to discover the optimum or workable ranges by routine experimentation" wherein the general conditions of a claim are disclosed in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan "Paddy" Sreenivasan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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